CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
BOARD OF PHARMACY

TELEPHONE: (302) 744-4500
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WEBSITE: DPR.DELAWARE.GOV
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APPLICATION FOR OUTSOURCING FACILITY PERMIT
INSTRUCTION SHEET

When to File Application

A facility that holds, or has applied for, a Delaware In-State or Non-Resident Pharmacy license or a Delaware Distributor license must also hold a Delaware Outsourcing Facility permit when the facility:

- compounds sterile drugs without a prescription, and
- distributes the compounded drugs to Delaware.

The facility must comply with the requirements of Section 503B, *Registration of Outsourcing Facilities and Reporting of Drugs*, of the federal Food, Drug, and Cosmetics Act.

File this form to apply for an initial Outsourcing Facility permit OR to re-apply when a previous Outsourcing Facility permit has lapsed and is no longer renewable. The facility must hold a current Delaware In-State Pharmacy, Non-Resident Pharmacy or Distributor license or apply for one of these licenses concurrently with this application for the Outsourcing Facility permit.

Since Outsourcing Facility permits are not transferable, you must also file this application to report when an Outsourcing Facility *already* licensed in Delaware:

- changes ownership (controlling interest), or
- relocates.

An Outsourcing Facility permit terminates automatically when the:

- facility's Delaware In-State Pharmacy, Non-Resident Pharmacy or Distributor license terminates for any reason, or
- controlling interest in the facility changes, or
- facility's legal existence ends, or
- business ceases to operate (24 *Del. C*. §2540 (d)).

Requirements for All Applicants

Please read and follow instructions carefully. Failure to follow instructions may delay your application.

☐ Submit completed, signed and notarized *Application for Outsourcing Facility Permit*.
- Applications that are incomplete, unsigned or not notarized will be rejected.

☐ Enclose non-refundable processing fee by check or money order made payable to the "State of Delaware."

☐ If the facility has registered with the Food and Drug Administration or Drug Enforcement Administration, enclose results of the most recent Good Manufacturing Practice (GMP) inspection.

Inspection Requirement for In-State Pharmacies and Distributors

In addition to meeting the requirements above, an inspector representing the Delaware Board of Pharmacy must inspect an outsourcing facility physically located in Delaware before beginning compounding operations. A representative of the facility must notify the Board office when the facility is ready for inspection. When the facility passes the final inspection, the Board office will issue the license. This Delaware inspection does ***not*** apply to facilities that are compounding at a location outside Delaware.

> ***Note:*** This Delaware inspection is *in addition to* the required federal outsourcing facility inspection.

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APPLICATION FOR OUTSOURCING FACILITY PERMIT

TYPE OF APPLICATION

1. Select the items that describe the type of application:

☐ Initial Application for Outsourcing Facility permit – check *one* of the following:

☐ This facility *currently holds* a Delaware In-State Pharmacy, Non-Resident Pharmacy or Distributor license number A __ - _____

☐ This facility has *applied for* a Delaware In-State Pharmacy, Non-Resident Pharmacy or Distributor license.

☐ This facility *previously held* a Delaware In-State Pharmacy, Non-Resident Pharmacy or Distributor license number A __ - _____ that has lapsed and is no longer renewable. ***Note***: You must reapply for an In-State or Non-Resident Pharmacy or Distributor license.

☐ Application Due to Change of Ownership of Outsourcing Facility, Delaware Outsourcing Facility permit number AA - _____ ***Note***: You must also file an application for the In-State or Non-Resident Pharmacy or Distributor license.

☐ Application Due to Relocation of Outsourcing Facility, Delaware Outsourcing Facility permit number AA - _____ ***Note***: You must also file an application for the In-State or Non-Resident Pharmacy or Distributor license.

2. Check all outsourcing services offered:

☐ Compound and distribute *non-controlled* sterile substances

☐ Compound and distribute *controlled* sterile substances

CONTACT AND LOCATION INFORMATION

3. Name of Business: _____
This ***must*** be the same name that appears on this facility's Pharmacy or Distributor license.

4. Enter all other trade or business names you use (or have used) such as "doing business as" or "formerly known as" names: _____ _____ _____

5. ***Location (Site of Compounding)*** **Address**: _____
Street (*No PO Boxes*)

_____ _____ _____
City State Zip

6. Phone: _____ Email: _____

7. ***Mailing*** **Address** (*if different from physical location*): _____

_____ _____ _____
City State Zip

8. Name of Contact Person: _____ ☐ Owner ☐ Manager ☐ Other

9. Phone (*if different from physical location*): _____ Email: _____

FEDERAL COMPLIANCE

10. Is this facility registered with the Food and Drug Administration (FDA) as required by Section 503B, *Registration of Outsourcing Facilities and Reporting of Drugs*, of the federal Food, Drug, and Cosmetics Act? Yes ☐ No ☐ If yes, enter the FDA registration number: _____

11. Has this facility passed an FDA inspection as required by Section 503B, *Registration of Outsourcing Facilities and Reporting of Drugs*, of the federal Food, Drug, and Cosmetics Act? Yes ☐ No ☐ **If yes, enclose results of the most recent Good Manufacturing Practice (GMP) inspection**.

When your application is complete, please allow 4-8 weeks to receive your license. A complete application is one that includes all required documentation and correct payment. Applications that are not complete within six months of filing may be considered abandoned and discarded.

AFFIDAVIT

I do hereby make application to the Board of Pharmacy for a permit under the provisions of an Act to regulate the practice of Pharmacy in the State of Delaware and I solemnly swear and affirm that the answers to the questions set forth in this application are true and correct.

Printed Name: _____ Title: _____

Signature: _____ Date: _____

State of _____ County of _____

Subscribed and sworn to before me this_____day of_____, 2_____

Witness my hand and seal hereunto attached.

Notary Signature:_____

SEAL

My Commission expires: _____

APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED PROCESSING FEE WILL BE REJECTED.